SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

Subpart B—Quality Standards and Certification

AUTHORITY: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

EFFECTIVE DATE NOTE: At 62 FR 55976, Oct. 28, 1997, part 900 was revised; and at 62 FR 60614, Nov. 10, 1997, it was republished and corrected, effective Apr. 28, 1999, with excepted provisions effective Oct. 28, 2002. For the convenience of the user, revised and corrected part 900 follows the text of this part.

Subpart A—Accreditation

SOURCE: 58 FR 67562, Dec. 21, 1993, unless otherwise noted.

§900.1 Scope.

The regulations set forth in this part implement 42 U.S.C. 263b(b) through (f). The intent of subpart A of this part is to establish application procedures for accrediting bodies and to establish requirements and standards for such bodies to ensure that all mammography facilities in the United States are adequately and consistently evaluated for compliance with quality standards for mammography. The intent of subpart B of this part is to establish procedures for facility certification and to establish quality standards for mammography facilities to assure safe, reliable, and accurate mammography on a nationwide level.

§900.2 Definitions.

The following definitions apply to subparts A and B of this part:

(a) *Accrediting body* or *body* means an entity that has been approved by FDA under 42 U.S.C. 263b(e)(1)(A) to accredit mammography facilities.

(b) *Certificate* means the certificate described in 42 U.S.C. 263b(b)(1).

(c) *Certification* means the state of approval of a facility by FDA to provide screening and diagnostic mammography services.

(d) *Clinical image* means a mammogram.

(e) *Facility* means a hospital, outpatient department, clinic, radiology practice, or mobile unit, office of a physician, or other facility that conducts breast cancer screening mammography activities or conducts diagnostic mammography activities, including the following: The operation of equipment to produce a mammogram, processing of film, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(f) *Interpreting physician* means a physician who interprets mammograms made during screening or diagnostic mammography procedures and who meets the requirements of §900.12(a)(1).

(g) *Mammogram* means a radiographic image produced through mammography.

(h) *Mammography* means radiography of the breast.

(i) *Medical physicist* means a person meeting the qualifications for a medical physicist set forth in §900.12(a)(3).

(j) *Patient* means any individual who undergoes clinical evaluation in a mammography facility, regardless of whether the person is referred by a physician or is self-referred.

(k) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and